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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,242	12/06/2000	David M. Kranz	89-99	8588

23713 7590 02/26/2003

GREENLEE WINNER AND SULLIVAN P C  
5370 MANHATTAN CIRCLE  
SUITE 201  
BOULDER, CO 80303

EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/26/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/731,242

Applicant(s)

KRANZ ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2002 and 11 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6-10, 13, 14 and 24-106 is/are pending in the application.
- 4a) Of the above claim(s) 6-10, 13, 14, 24-37 and 58-103 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-47 is/are allowed.
- 6) ☒ Claim(s) 38-43, 48-57 and 104-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/6/00 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>15</u> . | 6) <input type="checkbox"/> Other:  |

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### Detailed Action

It is noted that the Tables on pp. 35-38 of the instant specification have been determined by the Office of Initial Patent Examination (OIPE) as not suitable for printing and will have to be canceled and resubmitted as Figures.

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 48-57 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically claims 48-57 recite T cells expressing on their surfaces high affinity TCRs. The T cells are not claimed as being isolated or *in vitro* and so the claimed subject matter can read on T cells *in vivo*. The specification indeed contemplates that the T cells can be *in vivo*. The claims therefore can be read to include a human being containing the T cells because the claims read on cells making up a portion of a human being. Claims reading on human beings are non-statutory subject matter. Redrafting the claims to recite T cells *in vitro* or isolated T cells would be remedial.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 48-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants claim T cells expressing on their surfaces high affinity TCRs. The claims read on a T cell in an *in vitro* or *in vivo* environment. If the cell is present in an *in vivo* environment, the claims are vague in that the metes and bounds of the claimed subject matter are unclear. It is unclear if applicants are claiming a cell within a subject or the subject him or herself because the cell in an *in vivo* environment is a part of the subject.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 38-43, 48-53 and 104-106 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim soluble high affinity TCRs or T cells expressing high affinity TCRs exhibiting a dissociation constant for a given ligand (which can be a peptide/MHC ligand or a superantigen) of from about  $10^7$  to  $10^{10} \text{ M}^{-1}$ . The claims read on a genus of soluble high affinity TCRs and T cells expressing high affinity TCRs directed against any antigens.

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The written description requirement for a claimed genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicant was in possession of the claimed genus. In the instant case, applicants do not apparently disclose any specific soluble TCRs or T cells expressing TCRs on their surface which bind to ligands with the recited dissociation constants. No soluble TCRs or T cells expressing high affinity TCRs with the recited dissociation constants directed against a peptide/MHC ligand or a superantigen ligand are disclosed. It is noted that applicants disclose some examples of TCRs with high affinity for certain ligands but it is unclear what the dissociation constants for the binding between the ligands and TCRs are. Even if one or more of the disclosed soluble TCRs or TCRs expressed on T cells is subsequently determined to have a dissociation constant within the recited range, the claims would be described only with regard to that TCR. Applicants have presented no disclosed or art recognized nexus between the structure of the recited TCRs and their ability to bind to a given ligand with a dissociation constant of between  $10^7$  to  $10^{10} \text{ M}^{-1}$ . Given the absence of any disclosed examples of the recited invention and the absence of a disclosed or art recognized correlation between the structure of the recited TCRs and their function of binding to ligands with the recited dissociation constants, it must be considered that the skilled artisan would not conclude that applicants were in possession of the claimed genus.

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Any rejections not repeated in this Office Action are withdrawn.

Claims 44-47 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the Examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1096.

David Guzo  
February 21, 2003

DAVID GUZO  
PRIMARY EXAMINER  
